

**UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF NEW YORK**

ASSOCIATION FOR MOLECULAR
PATHOLOGY, *et al.*,

Plaintiffs,

v.

UNITED STATES PATENT AND
TRADEMARK OFFICE, *et al.*,

Defendants.

09-CV-4515 (RWS)

MEMORANDUM OF LAW OF
AMICI CURIAE IN SUPPORT OF
MOTION FOR LEAVE TO FILE
BRIEF AMICUS CURIAE IN
SUPPORT OF PLAINTIFFS

**MEMORANDUM OF LAW OF THE INTERNATIONAL CENTER FOR
TECHNOLOGY ASSESSMENT, INDIGENOUS PEOPLES COUNCIL ON
BIOCOLONIALISM, GREENPEACE AND THE COUNCIL FOR RESPONSIBLE
GENETICS IN SUPPORT OF THE MOTION FOR LEAVE TO FILE BRIEF
AMICUS CURIAE IN SUPPORT OF PLAINTIFFS**

Proposed *Amici Curiae* International Center for Technology Assessment (“ICTA”), Indigenous Peoples Council on Biocolonialism (“IPCB”), Greenpeace, and Council for Responsible Genetics (“CRG”) submit this memorandum of law in support of their motion to leave to file a brief *amicus curiae*.

I. INTRODUCTION AND INTERESTS OF PROPOSED *AMICI CURIAE*

Amici Curiae seek leave to file their proposed brief *amicus curiae*, submitted concurrently herewith, in order to assist the Court in understanding many of the important and complex issues concerning the patentability of human genes, new methods of looking at human genes, and the concept of comparing different gene sequences.

This case concerns the validity of patent claims over gene sequences associated with breast and/or ovarian cancers, methods of examining human gene sequences, and the

concept of comparing one gene sequence to another. One of the *Amici Curiae*, ICTA, was formed in 1994 with the primary mission of assisting the public and policymakers to better understand how technology affects society. ICTA's Patent Watch Project works to expose and to challenge the inappropriate use of the United States patent system by initiating and supporting legal challenges against existing and future pernicious patents. In particular, the ICTA's Patent Watch Project has successfully challenged the validity of patents granted on various plants and animals, such as animal organ mutations and animal immune systems.

Amicus Curiae CRG is a national non-profit organization founded in 1983 to represent the public interest and foster public debate about the social, ethical, and environmental implications of genetic technologies. CRG works with a coalition of health and patient advocacy groups to build support for a ban on gene patents by identifying and explaining the practical risks of patenting for innovation and the necessity for the open exchange of scientific data. CRG staff and board members have testified before Congress, Federal agencies, regulatory bodies, and state legislatures on the impacts of genetic technology developments. The CRG also publishes a magazine, *GeneWatch*, that regularly includes articles by experts in the field on issues related to gene patents.

Amicus Curiae IPCB assists indigenous people in the protection of their genetic resources against the negative impacts of genetic research. IPCB is concerned with the cultural and social impacts of gene patents upon the rights of indigenous peoples.

Amicus Curiae Greenpeace, a global environmental organization, has done substantial study into the economic costs of the privatization of human genes through

patents. Greenpeace believes that patents on genes, plants, humans, and parts of the human body, if unregulated, adds a significant cost to society as a whole.

Amici Curiae argue that Defendant's patent claims at issue here are based on unpatentable subject matter because they are products of nature. Furthermore, *Amici* demonstrate that enforcement of these restrictive patent claims will have a negative impact on scientific research and harm the interests of society at large. *Amici* also illustrate the broader implications of this case on genetics as a common heritage, the particular interests of indigenous peoples and the rights of patients to informed consent. *Amici Curiae* seek to provide this Court with insights into the broader adverse effects of gene patents on society.

II. ARGUMENT

"A district court has broad discretion to grant or deny an appearance as amicus curiae in a given case." *Citizens Against Casino Gambling in Erie County v. Kempthorne*, 471 F.Supp.2d 295, 311 (W.D.N.Y.2007) (citing *United States v. Ahmed*, 788 F.Supp. 196, 198, n. 1 (S.D.N.Y.1992), *aff'd*, 980 F.2d 161 (2d Cir.1992)). "The amicus privilege 'rests in the discretion of the court which may grant or refuse leave according as it deems the proffered information timely, useful, or otherwise.'" *Long Island Soundkeeper Fund, Inc. v. New York Athletic Club of the City of New York*, 1955 WL 358777, at *1 (S.D.N.Y. 1995) (citing *Leigh v. Engle*, 535 F. Supp. 418, 420 (N.D. Ill. 1982)). Accordingly, "parties should have their 'dispute resolved without any unnecessary delay.'" *Andersen v. Leavitt*, 2007 WL 2343572, at *6 (E.D. N.Y. 2007) (citing *Long v. Coast Resorts, Inc.*, 49 F.Supp.2d 1177, 1178 (D.Nev.1999)). Even where cross-motions for summary judgment had already been filed, but no judgment was

rendered, amicus status may be granted if it will not delay the court's judgment. *See Andersen*, 2007 WL 2343572 at *6; *see also Fluor*, 35 Fed. Cl. at 286 (filing amicus curiae brief in midst of briefing cross motions for summary judgment acceptable).

“The primary reason to allow *amicus curiae* briefing is that the *amicus curiae* offer insights not available from the parties, thereby aiding the Court.” *Andersen*, 2007 WL 2343572 at *2 (citing *Citizens Against Gambling*, 471 F.Supp.2d at 311 (further citation omitted)).

An *amicus* brief should normally be allowed when a party is not represented competently or is not represented at all, when the *amicus* has an interest in some other case that may be affected by the decision in the present case (though not enough affected to entitle the *amicus* to intervene and become a party in the present case), or when the *amicus* has unique information or perspective that can help the court beyond the help that the lawyers for the parties are able to provide. *Anderson* at *2 (quoting *Ryan v. Commodity Futures Trading Comm'n*, 125 F.3d 1062, 1063 (7th Cir. 1997)).

This case concerns the enforceability and validity of patent claims covering DNA sequences of genes associated with breast and/or ovarian cancers. The case specifically concerns the harm caused to patients and to the general public by patents granted on BRCA1 and BRCA2 genes. However, the outcome of this case will have much a much broader impact on the scope of patentable subject matter, particularly regarding unpatentable laws of nature, products of nature, and abstract ideas. The outcome of this case will broadly affect the rights of countless peoples who will be directly and indirectly impacted by the brand of patents challenged herein. *Amici Curiae* have unique expertise and perspectives that will assist the Court by providing useful information on the scientific, cultural, social, environmental and economic effects of gene patents, including the patents on BRCA1 and BRCA2 genes as well as the many other genes that will be

affected by the outcome of this case. Because of the importance of this case and the substantial interests and unique information of the proposed *Amici Curiae* the Court should exercise its discretion to allow *Amici Curiae* to file the proposed brief *amici curiae* in this case.

III. CONCLUSION

For the foregoing reasons, *Amici Curiae* respectfully request that the Court grant their Motion for Leave to File Brief *amicus curiae*.

Respectfully submitted,

Dated: September 10, 2009

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